

**FINAL STATEMENT OF REASONS**  
**22 CALIFORNIA CODE OF REGULATIONS**  
**SECTION 12601. CLEAR AND REASONABLE WARNINGS**  
**SECTIONS 12201. DEFINITIONS**

Update of Information to the Initial Statement of Reasons

**TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS, OR DOCUMENTS**

Except for the reference to existing definitions in Business and Professions Code Section 1741(e) and Health and Safety Code Sections 1797.80, 1797.82, and 1797.84 and reliance upon Business and Professions Code Sections 1627.7(a) and 2397(a), no other technical, theoretical or empirical material was relied upon by OEHHA in proposing the adoption of these regulations.

**REASONABLE ALTERNATIVES TO THE REGULATION AND THE AGENCY'S REASONS FOR REJECTING THOSE ALTERNATIVES**

At the time the Notice of Proposed Rulemaking and Initial Statement of Reasons were made available on July 27, 2001, OEHHA was not aware of any alternatives to the proposed regulatory action. Alternatives were suggested during the 45-day public comment period and the 15-day public comment period and are addressed within the summary and response to comments section of this document.

**REASONABLE ALTERNATIVES TO THE PROPOSED REGULATORY ACTION THAT WOULD LESSEN ANY ADVERSE IMPACT ON SMALL BUSINESS**

The proposed regulatory action will not adversely impact small business. The proposed regulatory amendment identifies under which specific emergency circumstances the accepted practice of obtaining informed consent from patients would satisfy the Proposition 65 warning requirement. The proposed regulatory amendment does not impose any requirement upon any business, including small business.

**EVIDENCE SUPPORTING FINDING OF NO SIGNIFICANT ADVERSE ECONOMIC IMPACT ON ANY BUSINESS**

The proposed regulatory amendment identifies under which specific emergency circumstances the accepted practice of obtaining informed consent from patients would satisfy the Proposition 65 warning requirement. No costs or expenses are incurred by businesses to comply with the proposed regulatory amendment. There is no significant adverse economic impact on any business. In fact, the proposed regulatory action makes it easier for affected businesses to comply with Proposition 65.

## **AVOID UNNECESSARY DUPLICATION OR CONFLICTS WITH FEDERAL REGULATIONS**

The Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65 or the Act), is a California law that has no federal counterpart. There are no federal regulations addressing the same issues and thus, there is no duplication or conflict with federal regulations.

## **BACKGROUND**

Proposition 65 prohibits a person in the course of doing business from knowingly and intentionally exposing any individual to a chemical that has been listed as known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual (Health and Safety Code Section 25249.6.) Implementing regulations were adopted in Title 22, California Code of Regulations, Section 12601 (unless otherwise specified, all section references are to Title 22, California Code of Regulations) to interpret and make specific the “clear and reasonable” warning requirement.

The existing regulation establishes the language and methods of transmitting a warning which are deemed to be in compliance with the clear and reasonable warning requirement specified in the Act. Currently, the regulations establish “safe harbor” language for consumer product exposures, occupational exposures, and environmental exposures. (The optional “safe harbor” warning language means that the warning given is “clear and reasonable.”) A warning is considered “clear” if it clearly communicates that the chemical in question is known to the State to cause cancer, or birth defects or other reproductive harm and is “reasonable” if the method employed to transmit the message is reasonably calculated, considering the alternative methods available under the circumstances, to make the warning message available to the individual prior to exposure. Warnings of exposures to chemicals listed under the Act are required to be given without qualification before an exposure above specified risk levels occurs.

In February 2000, the Office of Environmental Health Hazard Assessment (OEHHA) received a petition from the Advanced Medical Technology Association filed pursuant to Government Code Section 11340.6 proposing specific amendments concerning medical devices to the warning regulation under Proposition 65 (Section 12601). The petition sought to have OEHHA adopt a regulation requiring passage of the warning from the manufacturer through the distribution chain to the health care provider to the patient; amendments that differentiate between the categories of medical devices (prescription, non-prescription, and in vitro diagnostic); and specific warning language applicable to all medical devices. OEHHA convened a public workshop on September 21, 2000 to solicit input on the need for the proposed amendments. After carefully reviewing the petition and the oral and written comments received on the subject, OEHHA denied the requests for generalized warning regulations pertaining to all medical devices. OEHHA determined that the petition was overly broad and did not provide an adequate basis for creating unique warning rules for virtually all medical device products. OEHHA, however, did believe there was merit to the development of a regulation that addressed the administering of Proposition 65 warnings to an unconscious patient, a patient undergoing an urgent medical procedure, and a person who is legally incapable of giving consent. OEHHA recognizes that there are some emergency situations in which a prior Proposition 65 warning by the person responsible for an exposure to a listed chemical is not possible. Accordingly, OEHHA proposes to amend Section 12601(b)(2) to

identify under which emergency situations the accepted practice of obtaining a patient's informed consent would be deemed to be in compliance with the warning requirement of Proposition 65.

#### Section 12601

The proposed amendment to Section 12601(b)(2) relies upon the accepted practice of medical and dental personnel to obtain a patient's informed consent to constitute compliance with the Proposition 65 warning requirement. OEHHA recognizes that there are emergency situations that require immediate medical or dental services to alleviate severe pain, or to preserve life and limb. A delay in administering services may be detrimental to the well being of the patient. It is for these types of situations that OEHHA proposes to adopt the current medical and dental practice of obtaining a patient's informed consent as a means of complying with the Proposition 65 warning requirement. Thus, no additional warnings beyond those required under the doctrine of informed consent are required.

#### Section 12201

The phrase, "includes, but is not limited to," as referred to in the definitions for "medical personnel," "dental personnel," and "certified emergency medical personnel" is deleted in response to a comment received during the 45-day public comment period that stated the phrase made the definitions unclear and subject to abuse.

### **SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE INITIAL NOTICE PERIOD OF JULY 27, 2001 THROUGH SEPTEMBER 10, 2001**

**COMMENT 1a:** Environmental Defense (See Comment 1, p. 1) strongly objected to the form of the proposed regulations, which purport to create an "exemption" from Proposition 65 warning requirements. Regulations may not create exemptions from mandatory statutory duties. Amendments to the regulations may be adopted to address special emergency circumstances in a way that furthers the interests of the statute.

**RESPONSE:** OEHHA accepts the comment and accordingly modified the proposed regulatory text and made such changes publicly available via the 15-day notice of modifications. As initially proposed, under specific emergency circumstances, a clear and reasonable warning was not required, arguably exceeding the lead agency's statutory authority. Instead, the proposed regulatory text was modified to borrow and rely upon the concept of "informed consent." Thus, the accepted practice of obtaining a patient's informed consent when similar specific emergency circumstances exist is recognized in the regulation as a means of complying with the clear and reasonable warning requirement.

**COMMENT 1b:** Environmental Defense (See Comment 1, p. 2) stated that OEHHA may provide that "clear and reasonable warning" can be given only after-the-event because before-the-event warning is physically unreasonable or impossible. After-the-event warnings would not have to be identical to other Proposition 65 warnings. OEHHA may define a special method of satisfying the warning obligation that applies under emergency circumstances.

**RESPONSE:** OEHHA rejects the comment. OEHHA agrees that a primary purpose of the warning is to give one an opportunity to make an informed decision about whether to subject oneself to the exposure to the chemical in question. An after-the-event warning would not allow for informed decision-making on the part of the individual. This is because the decision had already been made for the individual by attending emergency personnel with the individual's best interest in mind. Instead, the regulation considers that for possible future exposure events of a non-emergency nature, perhaps to the same chemical in question, a Proposition 65 warning may be given at that time, if warranted. It would provide a more meaningful opportunity for an individual to decide about his or her chemical exposure.

**COMMENTS 1c and 1d:** Environmental Defense (See Comment 1, pp. 2 and 3) stated that the proposed Sections 12601(b)(6)(A)(2) and (3) are overbroad and unnecessarily ambiguous in two aspects. One, in the definitions of designated personnel in proposed Section 12201(m), (n), and (o), the phrase, "includes, but is not limited to," makes the definition unclear and subject to abuse. Environmental Defense urged that the definitions be limited to specified personnel or be extended to other specified personnel that can be identified with sufficient clarity to insure that such personnel have had sufficient emergency training. Two, in proposed Sections 12601(b)(6)(A)(2) and (3), the connection between the immediacy of the need for the procedure and insufficiency of time to fully inform the patient are ambiguously linked and should be made clear. Alternative language was suggested.

**RESPONSE:** OEHHA accepts the first aspect of the comment and deletes the phrase, "includes, but is not limited to," from the specified subsections. OEHHA accepts in part the second aspect of the comment. The phrase, "responsible for administering the care," is added to the respective subparagraph to clarify which medical, dental, and emergency personnel are referred to in the proposed regulations. The other suggested language changes of "must," "so," and "that" are rejected because OEHHA does not wish to make a change from the existing analogous statutory language and the understood practice of identified emergency circumstances already recognized by the medical and dental professions.

**COMMENT 1e:** Environmental Defense (See Comment 1, p. 3) stated that all references to "exemption" within the text of the Initial Statement of Reasons should be deleted.

**RESPONSE:** The Initial Statement of Reasons is a separate and required document of the rulemaking package. Changes cannot be made to the language within the Initial Statement of Reasons after its publication as part of the Notice of Proposed Rulemaking. However, as explained in the previous response to Comment 1a, OEHHA acknowledges that it does not have the authority to create an "exemption" from the warning requirement; and therefore, modified the regulatory language to eliminate the reference to an "exemption" in the proposed regulations.

**COMMENT 2:** National Association of Dental Laboratories (See Comment 2, pp. 1 and 2) stated that there "currently does not exist a passage of the warning from the manufacturer through the distribution chain to the health care provider to the patient of federally required items which a dentist must disclose in order to obtain informed consent..." The commenter further states this presents two problems: 1) dentists, dental staff and patients are not provided with information necessary for their protection in the event the dental prosthesis must be adjusted; and 2) dentists, dental staff, and patients are not receiving information related to FDA product recalls or OSHA

Material Usage Warnings because there is no system to track products from manufacturer to the end user. The commenter believes it is in the patient's best interest to provide a defined chain of distribution for clear and reasonable warnings to patient and the occupational dental staff.

**RESPONSE:** OEHHA rejects the comment. The comment is outside the scope of this rulemaking package. In addition, OEHHA lacks the authority to make the suggested change. A statutory change would be necessary to require that a warning regarding dental products be passed through the chain of distribution.

**COMMENT 3a:** Livingston and Mattesich (See Comment 3, p. 2) on behalf of AdvaMed support the adoption of the medical emergency regulations. While this regulation does not address the more significant concern of how to provide warnings to exposures resulting from the general use of medical devices, this proposal is a beneficial clarification and the commenter urges the adoption of the proposal.

**RESPONSE:** OEHHA accepts the comment. No further response is needed.

**COMMENT 3b:** Livingston and Mattesich (See Comment 3, p. 2) on behalf of AdvaMed in writing and through oral testimony at the public hearing on September 10, 2001 (See Transcript, p. 5) urged OEHHA to consider in the near future adopting regulations that will clarify how warnings are to be provided to patients exposed to listed chemicals from the broader use of medical devices. The commenter also urged OEHHA to convene a working group of health care providers and device manufacturers to provide input to develop a medical device clarifying regulation.

**RESPONSE:** OEHHA acknowledges the need for other clarifying amendments to the regulations. OEHHA plans to introduce other targeted rulemaking packages as a series of Proposition 65 regulatory amendments during the next several years. OEHHA has begun with minor changes of a less complex nature and will progress to more significant regulatory amendments. OEHHA has not yet determined whether such future regulatory amendments will address the warning requirement as it applies more generally to exposures to listed chemicals from medical devices.

**COMMENT 4a:** California Medical Association (See Comment 4, p. 1) provided its understanding of the workings of the doctrine of informed consent. The commenter observed that physicians are in the best position to determine which warnings should be given to patients.

**RESPONSE:** OEHHA notes that the commenter does not specifically urge any particular change to the proposed rulemaking. Thus, no change is made in response to this comment. In addition, OEHHA points out that Proposition 65 is a separate statutory scheme that operates independently from the doctrine of informed consent. The requirement to provide a clear and reasonable warning for all exposures (above specified risk levels) is specified in the Act. The Proposition 65 warning regimen applies to all circumstances where there is exposure above a specified risk level to a listed chemical. Therefore, it may, and does, require warnings in some instances in which a separately operating warning (or labeling) regimen may not require a warning. The fact that a physician may feel he or she is in "the best position" to decide which warnings, if any, ought to be given to a patient is not controlling for purposes of Proposition 65. OEHHA has no authority to create an exemption from this requirement, as is implicitly urged by the commenter.

**COMMENTS 4b and 6b:** California Medical Association (See Comment 4, p. 2) again does not seek a specific change, but argues that the provision of a Proposition 65 warning may be deleterious to patients, and is medically unnecessary. Foley and Lardner on behalf of HCA, Inc. (See Comment 6, p. 2) made a similar comment, but went further to caution OEHHA not to regulate in a manner that weakens informed consent or that harms patients.

**RESPONSE:** The commenters have not sought a specific change to the regulations, and none is being made in response to this comment. In addition, as pointed out in the previous response to Comment 4a, OEHHA determined that it does not have the authority to create an exemption of the type implicitly sought by the commenters.

**COMMENTS 4c and 5b:** California Medical Association (See Comment 4, p. 2) opposes the medical emergency exemption proposed in 22 CCR Section 12601(b)(6) for two reasons. The first is that such a provision is unnecessary since physicians are already governed by informed consent rules and practices. Second, the commenter argues that by exempting health practitioners from providing a Proposition 65 warning during emergencies, implies that practitioners have a duty to provide a Proposition 65 warning under all non-emergency situations. The commenter again argues that this may be medically unnecessary. California Healthcare Association (See Comment 5, p. 2) similarly was concerned that this regulation creating an exemption during emergency situations, would lead to an inference that health care providers must provide warnings in non-emergency situations.

**RESPONSE:** OEHHA has modified the proposed regulatory amendment to eliminate the exemption from the warning requirement under the Act. Instead, it is clarifying that compliance with the notion of informed consent also satisfies the warning requirement under the Act. OEHHA disagrees that such a clarification is unnecessary. The comment is premised again on the view that consistent with the doctrine of informed consent the practitioner will provide a warning for all medically relevant risks. This overlooks the fact that Proposition 65 operates independently of the tort doctrine of informed consent and requires warnings in situations where they might not otherwise be provided or required under other regulatory schemes or principles. By way of clarification, OEHHA notes that generally practitioners do have to provide clear and reasonable warnings under the Act for knowing and intentional exposures above specified risk levels to listed chemicals. Again, this results from the simple application of Proposition 65 independent of the tort doctrine of informed consent. Therefore, the implication drawn by the commenter is accurate.

**COMMENTS 4d and 5c:** California Medical Association (See Comment 4, p. 3) and California Healthcare Association (See Comment 5, pp. 2 and 3) argue that the regulatory change being made would require third party medical personnel who are not the primary health providers (physicians) to provide warnings that are outside the scope of and inconsistent with the informed consent doctrine.

**RESPONSE:** OEHHA must point out that the clarifying regulatory changes do not impose any additional obligations on any medical personnel, including non-physician medical personnel. Rather, it clarifies that any and all medical personnel are deemed to be in compliance with Proposition 65 warning requirements if any of the attending medical personnel is in compliance with informed consent practices during an emergency situation.

**COMMENTS 4e and 6c:** California Medical Association (See Comment 4, p. 3) proposed that OEHHA amend Section 12601(b)(2) after the last sentence with the addition of the following:

“For prescription medical devices, the labeling approved or otherwise provided under federal law and the prescriber’s accepted practice of obtaining a patient’s informed consent shall be deemed to be a clear and reasonable warning. For over-the-counter drugs, the labeling approved or otherwise provided under federal law shall be deemed to be a clear and reasonable warning.”

In addition, Foley and Lardner on behalf of HCA, Inc. (See Comment 6, p. 2) proposed that OEHHA amend Section 12601(b)(2) to include prescription medical devices. That is, the provision that states compliance with the Food and Drug Administration (FDA) warning requirements for prescription drugs is deemed to satisfy Proposition 65 warning requirements would be amended to read:

“For prescription drugs and prescription medical devices, the labeling approved or otherwise provided under federal law and the prescriber’s accepted practice of obtaining a patient’s informed consent shall be deemed to be a clear and reasonable warning.”

**RESPONSE:** OEHHA rejects the comments. This proposed change was considered and rejected when OEHHA considered the February 2000 petition submitted by Advanced Medical Technology Association (AdvaMed). The petition sought the adoption of regulations that provided tailored warnings for medical device exposures. OEHHA rejected the adoption on the basis that it was considered overly broad. There are over 4,000 separate categories of medical devices, as reported by the petitioner, and that there was no supportable basis for adopting special provisions, such as that suggested by the commenter, for all medical device exposures. OEHHA still believes that there is not a demonstrated basis for providing a blanket warning for unspecified medical devices.

**COMMENTS 4f and 5a:** California Medical Association (See Comment 4, pp. 3 and 4) and California Healthcare Association (See Comment 5, pp. 1 and 2) point out that the Attorney General’s Office chose not to bring a case for failure to provide Proposition 65 warnings for nicotine patches, a product regulated by the federal Food and Drug Administration (FDA). The commenters go on to note these nicotine patches carry FDA-approved warnings and that Proposition 65 was preempted as to requiring additional warnings for these patches. California Medical Association urged that no Proposition 65 warnings be required for prescription medical devices and over-the-counter drugs because both of these products also fall under the purview of FDA and instead proposed regulatory language as follows:

“A warning pursuant to Health and Safety Code Section 25249.6 is not required in connection with the provision of medically necessary health care services.”

California Healthcare Association, alternatively, proposed that OEHHA amend Section 12601(b)(2) to include prescription medical devices. That is, the provision would read:

“For prescription drugs and prescription medical devices, the labeling approved or otherwise provided under federal law and the prescriber’s accepted practice of obtaining a patient’s informed consent shall be deemed to be a clear and reasonable warning.”

**RESPONSE:** It is clear from a review of the entire letter from the Attorney General’s Office regarding the nicotine patch issue (provided by the California Medical Association), that the Attorney General’s decision not to bring an enforcement case for failure to provide a Proposition 65 warning was based in substantial part on the fact that the FDA warning scheme specific to nicotine patches preempted warning requirements under State law. The Attorney General’s Office clearly analyzed only the nicotine patch warning regimen and specifically limited its conclusions to that one product. Accordingly, one cannot draw more general conclusions about FDA warning requirements for all other medical devices and over-the-counter drugs simply because they are also regulated by FDA. Also, in this regard, there has been no judicial determination that there is a “blanket” preemption of Proposition 65 for products subject to regulations by FDA. Furthermore, OEHHA lacks the statutory authority to exempt the requirement of Proposition 65 warnings for all unspecified medically provided health care services. The suggested change is overly broad and ambiguous in that it would provide a blanket “warning exemption” for such services. [See Response to Comments 4e and 6c on pp. 6 and 7.]

**COMMENT 4.1:** California Medical Association (See Comment 4.1, p.1) through an electronic mail note, expressed concern that the definition for “medical personnel” was overly broad and stated it would elaborate on its concern in other formal comments.

**RESPONSE:** The commenter did not provide further details on its concern over the definition for “medical personnel” in its formal comment. Nonetheless, in response to Comment 1c, for clarity OEHHA amended the definition of “medical personnel” to delete the phrase, “includes, but is not limited to.” No further response is needed.

**COMMENT 5d:** California Healthcare Association (See Comment 5, p. 3) states that California law already sets a standard regarding what information the patient must receive involving “material risks.” The commenter further states that there is a considerable body of case law defining and clarifying what does and does not constitute “material risk.” The proposed regulatory amendment does not incorporate the concept of “material risk,” and therefore is inconsistent with California law.

**RESPONSE:** OEHHA notes that the commenter does not specifically request any particular change to the proposed rulemaking. Thus, no change is made in response to this comment. In addition, OEHHA points out that Proposition 65 is a separate statutory scheme that operates independently from the doctrine of informed consent. The Proposition 65 requirement to provide a clear and reasonable warning for all exposures above specified risk levels, including those which may not constitute “material risk” for informed consent purposes is specified in the Act. OEHHA does not have the authority to create an exemption from this requirement. [See Response to Comments 4c and 5b on p. 6.]

**COMMENT 5e:** California Healthcare Association (See Comment 5, p. 3) pointed out that the proposed amendment failed to incorporate the concept of “therapeutic privilege,” a privilege physicians have to not disclose information regarding the nature of a proposed treatment, the risks and benefits, or the alternatives if to do so would cause the patient to be unable to rationally consider and make a decision about the proposed treatment.



**RESPONSE:** OEHHA notes initially that the comment appears to confuse what OEHHA is and is not doing by way of this rulemaking. Although OEHHA “borrows from” the concept of informed consent to clarify what behavior constitutes compliance with Proposition 65, OEHHA is not wholesale incorporating all aspects of the tort doctrine of informed consent into Proposition 65 – nor could it. That is, Proposition 65 is a stand-alone statutory scheme that has its own lawful status and operates independently of the rules of informed consent. Quite simply, the doctrine of informed consent neither conflicts with nor preempts Proposition 65. Thus, OEHHA lacks the authority to craft exemptions from the Proposition 65 warning requirements based on the fact that an activity may not be subject to the general requirement to obtain informed consent. Nor is the specific “therapeutic privilege” principle within the doctrine of informed consent relevant to the Proposition 65 warning regimen.

**COMMENT 5f:** California Healthcare Association (See Comment 5, p. 3) suggests that the proposed regulation be drafted to create an exemption from the Proposition 65 warning requirement with regard to all patients who lack the capacity to make health care decisions, not just unconscious patients.

**RESPONSE:** OEHHA is no longer proposing to create an exemption from the warning requirement. OEHHA has determined that it lacks authority to create an exemption from this requirement. Instead, OEHHA is proposing that compliance with the accepted practice of obtaining informed consent in emergency situations constitutes compliance with the clear and reasonable warning requirement of Proposition 65. More importantly, OEHHA notes that the regulatory clarification at 22 CCR Section 12601(b)(2)(B)(2)-(3) does apply to additional instances in which the patient lacks the capacity to give informed consent – not just when the patient is unconscious. More specifically, the regulation applies to emergency situations in which there is no time to provide the warning and to those situations in which the patient lacks the legal capacity to provide informed consent. Thus, no change is necessary to accommodate this comment.

**COMMENT 6a:** Foley and Lardner on behalf of HCA, Inc. (See Comment 6, p. 1), suggests the regulation is not necessary because “Informed consent, which is law in California, provides an exemption from providing health hazard information to emergency patients.”

**RESPONSE:** OEHHA disagrees that this regulatory clarification is not necessary. OEHHA notes the existence of the tort doctrine of informed consent, which has its origins as a defense to the tort of battery. However, OEHHA must point out that this tort defense does not preempt, or even conflict with, Proposition 65. More specifically, the fact that a health care practitioner may not have to provide a warning in a given circumstance under the concept of informed consent does not mean that no warning is required under Proposition 65. In fact, absent the clarification OEHHA is making here, health care practitioners have a separate and independent obligation to provide a Proposition 65 warning irrespective of whether the notion of informed consent would require a warning in the same circumstance. This is not unusual in the law; nor is it a prohibited outcome. For all of the above reasons, no change is being made to the regulations in response to this comment. [See Response to Comments 4c and 5b on p. 6, and Response to Comment 5d on p. 8.]

## **COMMENTS RECEIVED DURING THE PERIOD THE MODIFIED TEXT WAS AVAILABLE TO THE PUBLIC**

The modified text was made available to the public from February 11, 2002 through February 27, 2002. After the close of the comment period, OEHHA was contacted by an interested party and informed that several parties had not received the 15-day Notice of Modifications. Inadvertently, three interested parties that had made comments during the initial 45-day public comment period did not receive the 15-day Notice of Modifications. Therefore, OEHHA extended the Notice of Modifications comment period for the affected parties until April 10, 2002.

## **SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE 15-DAY NOTICE OF MODIFICATIONS PERIOD OF FEBRUARY 11, 2002 THROUGH FEBRUARY 27, 2002 (INCLUDES COMMENTS RECEIVED DURING THE EXTENDED COMMENT PERIOD)**

**POST-HEARING COMMENT 1a:** California Medical Association (See Post-hearing Comment 1, pp. 1 and 2) is concerned that the Proposition 65 warning obligation interferes with the physician-patient relationship, thereby impacting the quality of health care. The commenter goes on to say that the regulations address the doctrine of informed consent in a manner that does not make sense. More specifically, the commenter points out that Business & Professions Code Section 2397 already contains an exemption from the requirement to obtain informed consent in emergency situations.

**RESPONSE:** As noted in the previous response to comments, [See Response to Comment 4a on p. 5.] Proposition 65 exists as a statutory scheme separate and apart from the notion of informed consent. OEHHA acknowledges that Proposition 65 may require physicians and/or other health care practitioners to provide warnings in circumstances where they otherwise would not be required to do so. However, this results from the fact that Proposition 65 contains no blanket exemption for health care providers.

OEHHA also acknowledges that there are exceptions to the doctrine of informed consent currently in place.

**POST-HEARING COMMENT 1b:** California Medical Association (See Post-hearing Comment 1, pp. 2 and 3) reiterates its previously stated concerns about why the imposition of warnings within the context of providing medically necessary health care is not in the patient's best interest. The commenter goes on to outline how the doctrine of informed consent works, pointing out exceptions to the doctrine and observing that physicians are in the "best position" to determine which warnings should be given to patients. The commenter does not believe any Proposition 65 warnings that fall outside the scope of informed consent principles should be required and that the provision of such warnings can lead to "overwarning."

**RESPONSE:** OEHHA has previously responded to the commenter's concern that the provision of Proposition 65 warnings may not be in the patient's best interest. [See Response to Comments 4b and 6b on pp. 5 and 6.] OEHHA has also responded to the observation that physicians are in the best position to determine which warnings should be given to patients. [See Response to Comment 4a on p. 5.] OEHHA has also responded previously to the comments that Proposition 65 should not

require any warning in a medical setting that would not otherwise be required. [See Response to Comments 4c and 5b on p. 6.] Finally, OEHHA acknowledges there may be instances where concerns regarding sanctions/liability for failure to give a Proposition 65 warning may lead to “overwarning.” However, Proposition 65 does not contain any provisions indicating the fact that warnings are/are not required under a different regulatory regime constitutes an exemption to the Proposition 65 warning requirement. Two additional points are worth noting in this regard. First, the Attorney General has released draft regulations that in the context of settling a lawsuit would require that any warnings to be given must be “truthful.” This should somewhat diminish the number of instances in which “overwarnings” are provided. Finally, OEHHA has indicated its intention to continue with the adoption of additional clarifying regulations. It is anticipated that Section 12601 may be one of the provisions addressed as part of this ongoing regulation(s) clarifying effort.

**POST-HEARING COMMENT 1c:** California Medical Association (See Post-hearing Comment 1, p. 3) argues that the regulation is unnecessary since the doctrine of informed consent already requires the disclosure of material information to patients. In addition, the commenter is concerned that the explicit exempting of health care practitioners from giving Proposition 65 warnings during emergency situations, implies that practitioners have a duty to provide warnings during non-emergency situations. Further, the commenter is also troubled that the emergency “exemption” would require non-physician third party “medical personnel” to provide warnings that are outside the scope of informed consent.

**RESPONSE:** OEHHA has previously responded to the comment that the regulation is unnecessary since the doctrine of informed consent already requires the disclosure of material information to patients. [See Response to Comments 4c and 5b on p. 6, and Response to Comment 5d on p. 8.] OEHHA has also indicated that the inference drawn that non-emergency medical situations are generally subject to applicable Proposition 65 warning requirements is an accurate one. [See Response to Comments 4c and 5b on p. 6.] That is, there is no statutory exemption from the Proposition 65 warning requirement for such exposures. If the exposure to a listed chemical is over the specified risk level, a Proposition 65 warning is required. Finally, OEHHA has also indicated previously, the regulations do not impose warning requirements on non-physician medical personnel. [See Response to Comments 4d and 5c on p. 6.] Rather, if any of these identified personnel determines that the situation constitutes an emergency, then the provision specifying that no additional Proposition 65 warning need be given applies.

**POST-HEARING COMMENT 1d:** California Medical Association (See Post-hearing Comment 1, p. 4) suggested that the regulation be amended to provide that:

“The accepted practice of obtaining the patient’s informed consent shall be deemed to be a clear and reasonable warning in connection with the provision of medically necessary health care services.”

The commenter indicates this approach would be consistent with informed consent principles, which already governs disclosure of health risks, and would avoid possible confusion to the patient.

**RESPONSE:** OEHHA initially evaluated a petition to create an exemption from the Proposition 65 warning requirement for all exposures to listed chemicals from medical devices. Ultimately, OEHHA determined that no convincing demonstration was made that such a sweeping exemption was necessary or within OEHHA’s rulemaking authority. The same two points could be made in

response to this suggestion that is broader still. More specifically, OEHHA is not convinced that the provision of warnings within the informed consent scheme constitutes the entirety of situations in which Proposition 65 warnings should be given in the medical setting. Proposition 65 is not superseded or preempted by the existence of the informed consent doctrine. The drafters of Proposition 65 intended it as a statutory “overlay” to all of the other warning schemes in existence. Finally, OEHHA lacks the generalized authority to create such a blanket exemption. This stands in sharp contrast to the regulations proposed here that acknowledge the existence of another warning scheme and relies on its analogous provisions addressing situations in which there is no realistic ability to provide a clear and reasonable warning prior to the exposure to the listed chemical.

**POST-HEARING COMMENT 1e:** California Medical Association (See Post-hearing Comment 1, p.4) proposes as an alternative to the previous comment that OEHHA amend Section 12601(b)(1)(A) to provide that:

“For prescription drugs and medical devices, the labeling approved or otherwise provided under federal law and the prescriber’s accepted practice of obtaining a patient’s informed consent shall be deemed to be a clear and reasonable warning. For over-the-counter drugs, the labeling approved or otherwise provided under federal law shall be deemed to be a clear and reasonable warning.”

The commenter also reiterated the case in which the Attorney General chose not to bring an enforcement action against nicotine patch manufacturers. As stated by the commenter, the Attorney General noted that the federal Food and Drug Administration (FDA) had already examined and reviewed the issue and believed that the FDA’s actions preempted Proposition 65. For the same rationale, the commenter believes that warnings for prescription medical devices and over-the-counter drugs should similarly be preempted because they are also under the purview of the FDA.

**RESPONSE:** OEHHA notes that although the focus of this comment is outside the scope of this rulemaking, OEHHA has previously provided a response to this comment. [See Response to Comments 4e and 6c on pp. 6 and 7.] OEHHA also responded to a comment regarding the potential applicability of the nicotine patch situation to the situation at hand. [See Response to Comments 4f and 5a on pp. 7 and 8.] No further response is provided.

**POST-HEARING COMMENT 2a:** California Healthcare Association (See Post-hearing Comment 2, pp. 1 and 2) also referred to the case in which the Attorney General chose not to bring an enforcement action against nicotine patch manufacturers because the FDA had adopted a specific warning requirement for nicotine patches that preempted the warning requirement of Proposition 65. The commenter believed the same public policy issues applied to prescription medical devices because they are also regulated by the FDA. The commenter suggested the following amendment to Section 12601(b)(2):

“For prescription drugs and prescription medical devices, the labeling approved or otherwise required under federal law and the prescriber’s accepted practice of obtaining the patient’s informed consent shall be deemed to be a clear and reasonable warning.”

**RESPONSE:** California Healthcare Association submitted the same comment during the 45-day public comment period. OEHHA has previously responded to this comment. [See Response to Comments 4f and 5a on pp. 7 and 8.] No further response is provided.

**POST-HEARING COMMENT 2b:** California Healthcare Association (See Post-hearing Comment 2, p. 2) argued that the proposed language states that in the specified emergency circumstances, “the accepted practice of obtaining the patient’s informed consent shall be deemed to be a clear and reasonable warning...” is not workable. Instead, the commenter recommended the following revision to the proposed language in Section 12601(b)(2)(B):

“(B) For exposures resulting from emergency or urgent medical or dental care as defined in Section 12201(l), no warning shall be required when any of the following circumstances exist:...”

**RESPONSE:** OEHHA rejects the comment. OEHHA lacks the statutory authority to exempt the requirement of Proposition 65 warnings for all emergency medical or dental care. The suggested change is overly broad and ambiguous in that it would provide a blanket “warning exemption” for such emergency medical or dental services.

**POST-HEARING COMMENT 2c:** California Healthcare Association (See Post-hearing Comment 2, pp. 2 and 3) stated that the proposed rulemaking failed to incorporate the “therapeutic privilege” exception to the law of informed consent, and thus was inconsistent with current California law. The commenter recommended the following addition to Section 12601(b)(2)(B):

“4. The licensed medical personnel, licensed dental personnel, or certified emergency medical personnel responsible for administering care, as these terms are defined in Sections 12201 (m), 12201(n), and 12201(o), respectively, reasonably believe that giving a clear and reasonable warning would so seriously upset the patient (or of a person authorized to consent to the recommended treatment for the patient) that the patient (or the person authorized to consent to the recommended treatment for the patient) would not be able to dispassionately weigh the risks of refusing to undergo the recommended treatment.”

**RESPONSE:** OEHHA rejects the comment. As previously stated in the response to Comment 5e, OEHHA is borrowing from the concept of informed consent to clarify what behavior constitutes compliance with Proposition 65, OEHHA is not incorporating all aspects of the tort doctrine of informed consent into Proposition 65. Proposition 65 is a stand-alone statutory scheme that has its own lawful status and operates independently of the rules of informed consent. The doctrine of informed consent neither conflicts with nor preempts Proposition 65. OEHHA lacks the authority to adopt exemptions from the Proposition 65 warning requirements based on the fact that an activity may not be subject to the general requirement to obtain informed consent. The “therapeutic privilege” principle within the doctrine of informed consent is not specifically relevant to the Proposition 65 warning requirement.

**POST-HEARING COMMENT 2d:** California Healthcare Association (See Post-hearing Comment 2, p. 3) expressed concern that this rulemaking requires health care providers who are not primarily responsible for a patient’s treatment plan to provide Proposition 65 warnings in non-emergency situations.

**RESPONSE:** The clarifying regulatory changes do not impose any additional obligations on any medical personnel, including those not primarily responsible for a patient’s treatment. [See

Response to Comments 4d and 5c on p. 6.] Rather, it clarifies that any and all medical personnel are deemed to be in compliance with Proposition 65 warning requirements if any of the attending medical personnel is in compliance with informed consent practices during an emergency situation. For non-emergency situations, Proposition 65 operates independently of the tort doctrine of informed consent and requires warnings in situations where they might not otherwise be provided or required under other regulatory schemes or principles. OEHHA recognizes that health care providers have to provide clear and reasonable warnings under the Act for knowing and intentional exposures above specified risk levels to listed chemicals. This results from the application of Proposition 65 independent of the tort doctrine of informed consent.

**POST-HEARING COMMENT 2e:** California Healthcare Association (See Post-hearing Comment 2, p. 3) had previously expressed concern that California law already has a set standard regarding what information the patient must be given involving “material risks.” There is considerable case law defining “material risks” and what does and does not constitute “material risk.” The proposed rulemaking does not incorporate “material risk,” and therefore, is inconsistent with California law.

**RESPONSE:** OEHHA has previously responded to the issue of “material risk.” [See Response to Comment 5d on p. 8.] No further response is provided.

**POST-HEARING COMMENT 3:** HCA, Inc. (See Post-hearing Comment 3) represented by Nossaman, Guthner, Knox and Elliott (formerly represented by Foley and Lardner) reaffirms and resubmits its comments previously submitted during the 45-day public comment period. No new comments were submitted.

**RESPONSE:** OEHHA previously responded to HCA, Inc.’s comments [See Response to Comment 6a on p. 9, Response to Comment 6b on pp. 5 and 6, and Response to Comment 6c on pp. 6 and 7.] No further responses are provided.

**POST-HEARING COMMENT 4:** National Association of Dental Laboratories (See Post-hearing Comment 4)] resubmitted its previous comment submitted during the 45-day public comment period. No new comments were submitted.

**RESPONSE:** OEHHA previously responded to this comment [See Response to Comment 2 on pp. 4 and 5.] No further response is provided.

## **ALTERNATIVES DETERMINATION**

OEHHA has determined that no alternative would be more effective in carrying out the purpose for which the regulation is proposed or would be as effective and less burdensome to affected private persons than the proposed regulation.

## **LOCAL MANDATE DETERMINATION**

In accordance with Health and Safety Code Section 25249.11(b), the provisions of Proposition 65 do not apply to local, state or federal agencies. The proposed regulations do not impose any mandate on local agencies or school districts.

## **PROPOSED ALTERNATIVES THAT WOULD LESSEN ADVERSE ECONOMIC IMPACT ON SMALL BUSINESS**

The proposed regulatory action will not adversely impact small business. The proposed regulatory amendment identifies under which specific emergency circumstances the accepted practice of obtaining informed consent from patients would satisfy the Proposition 65 warning requirement. Thus, if anything, the proposed regulatory action makes it easier for affected small businesses to comply with Proposition 65. The proposed regulatory amendment does not impose any requirement upon any business, including small business.